



July 9, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1735-P
7500 Security Boulevard
P.O. Box 8013, Baltimore, MD 21244
Mail Stop C4-26-05

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals. (CMS–1735–P)

Dear Administrator Verma:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the proposed rule to revise the Medicare hospital inpatient prospective payments system (IPPS) for FY21.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC commends the Centers for Medicare & Medicaid Services' (CMS) continued commitment to coverage of innovative products such as creating a Medicare Severity- Diagnosis Related Group (MS-DRG) for CAR T-cell therapies as well as an expansion of technologies and treatments eligible to receive additional new technology add-on payments (NTAPs). These coverage determinations will help to ensure that patients can receive the most effective cutting-edge treatments available. We also support the

continued conversation around improving price transparency. It is important to give consumers the best tools available to determine individual health costs, but any changes should ensure that such information provides patients with accurate out-of-pocket cost information and does not interfere with proprietary business activities.

CAR T-cell Therapy MS-DRG

HLC is greatly appreciative of CMS' decision to create an MS-DRG to cover CAR T-cell therapies. Coverage of these treatments gives patients the opportunity to receive innovative treatments after all previous courses have failed. It is necessary that hospitals receive proper reimbursement for the use of these treatments. Creating an MS-DRG will build upon CMS' previous work to make CAR T-cell therapies available to more patients. HLC believes that it is crucial for CMS to ensure that hospitals and providers are receiving appropriate and adequate payment for providing these therapies.

The advances made in CAR T-cell therapies has resulted in a number of new therapies expected to come to market in the coming years. We hope that CMS will be mindful of these developments and ensure that any therapies that are approved by the Food and Drug Administration (FDA) receive immediate MS-DRG 018 status and that CAR-T clinical trial cases be permitted to utilize the unspecified ICD-10 code. This inclusion keeps in line with existing CMS coverage determinations and will allow for patients to be able to obtain quick access to these innovative and life-saving treatments.

New Technology Add-On Payments

HLC supports additional changes and clarifications to CMS' criteria for technologies and treatments to receive the additional NTAP. Given the current public health emergency, we support CMS' decision to include antibacterial and antimicrobial drugs as NTAP-qualified. CMS should additionally recognize the particular market challenges for novel antibiotics. Existing NTAPs for these products have had limited impact on their utilization and we encourage CMS to evaluate additional proposals to improve the use of such products.

We appreciate CMS seeking to accelerate payment for certain technologies that meet all new NTAP criteria, but have not received FDA marketing authorization by the July 1 cutoff. We encourage CMS to extend the accelerated payment opportunity to devices that receive FDA marketing authorization under the Breakthrough Devices program. Just as there is a need for expeditious access to antimicrobial products, there is a public health benefit to facilitating timely beneficiary access to technologies that the FDA determines meet Breakthrough Device standards, including providing for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions. Such access to NTAPs should also apply to drugs and biologics that have received similar status under existing FDA programs.

We also encourage CMS to explore issuing NTAP decisions semiannually, or quarterly, to expedite patient access to innovative technologies in the hospital setting and to more closely align application consideration to the date when evidence is available for CMS consideration. Any process in addition to the IPPS rule should also be transparent with a predictable timetable and opportunity for notice and comment.

Potential Change in Methodology for Calculation of MS-DRG Relative Weight

HLC supports efforts to create accurate rates that ensure proper reimbursement and steps to improve transparency that provides useful information to stakeholders about the potential cost and quality of their care. We recognize that efforts to improve transparency require some disclosure of certain data, but we encourage CMS to be mindful that any efforts to improve transparency do not interfere with proprietary business activities.

Under the proposed rule, CMS is considering a methodological change that would calculate MS-DRG weights by utilizing the rates hospitals negotiate with private insurers, including Medicare Advantage (MA) plans. CMS suggests that pegging the MS-DRG to negotiated rates would provide the most accurate payment rates under Medicare. HLC is appreciative of efforts to ensure payment rates are accurate so that providers can receive appropriate reimbursement. We understand that there may be opportunities to improve upon the current approach to setting payment rates in Medicare and would encourage CMS to work with providers, payors and other stakeholders to ascertain the best methodology for achieving accuracy in rate setting.

In order to determine the MS-DRG rate, CMS proposes to require that hospitals disclose the rates negotiated with private insurers, including MA plans. The stated justification behind this proposal is to create greater transparency about actual market costs and support the development of a market-based approach to payment under the Medicare fee-for-service system. HLC is concerned that exposing negotiated rates between hospitals and insurers would actually create a negative impact on pricing, as it may create a future floor for competitors to set their own negotiated rates with insurers.¹ Requiring disclosure of negotiated rates does not give patients a meaningful picture of the costs associated with certain types of care, as these rates do not reflect out-of-pocket costs. Moreover, extensive analysis of such a major change is needed before proceeding, as HLC is concerned that moving to this new methodology could cause wide swings in relative weights that could drastically alter hospital finances.

HLC supports initiatives that equip consumers with information on cost and quality without stifling price competition. We encourage CMS to pursue transparency initiatives that focus on giving consumers meaningful information about their personal costs

¹ Tara Isa Koslov & Elizabeth Jex, *Price Transparency or TMI? FED TRADE COMM'N* (June 19, 2020 4:45PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>.

allowing them to compare among providers and venues, and that are workable for the healthcare industry as a whole.

HLC looks forward to continuing to work with you on our shared priorities. Should you have any questions please do not hesitate to contact Tina Grande at (202) 449-3433 or tgrande@hlc.org.

Sincerely,

A handwritten signature in cursive script that reads "Mary R. Grealy". The signature is fluid and elegant, with the first letters of each word being capitalized and prominent.

Mary R. Grealy
President